

**REMARKS**

**Claim Status**

Claims 1-47 are pending in this application. Claims 1-47 have been rejected. Reconsideration of the application in view of the following remarks is respectfully requested.

**Claim Amendments**

Independent claim 1 has been amended to require that “the calcium carbonate is provided as a powder having a mean particle diameter from about 0.05  $\mu\text{m}$  to about 30  $\mu\text{m}$ .”

Dependent claim 10 has been cancelled.

Dependent claim 11 has been amended to change its dependency from cancelled claim 10 to independent claim 1.

Independent claim 36 has been amended to delete the phrase “wherein the baked product does not comprise spray-dried calcium citrate crystals.” While Applicants believe that the discussion of U.S. Patent No. 5,260,082 to delValle, et al. on page 6 of the specification fully supports the exclusion of spray-dried calcium citrate from the claims, the language has been deleted in order to advance prosecution of this case. Claim 36 has also been amended to require that the lower limit of calcium content is 1.2 % by weight.

No new matter is introduced by these amendments.

**Introduction**

Before discussing the specific rejections, Applicants wish to briefly discuss the claimed technology because it is apparent from the Office Action of February 1, 2006 that the Examiner is confusing the claimed acidic “suspensions” of calcium carbonate “powder” with the corresponding acid salts of calcium carbonate. For example, the Examiner states that

“Applicants are actually making calcium citrate or one of the other variations on the claimed acids” (p. 7). That is not the case.

Contrary to the Examiner’s assertion, Applicants’ claimed additive is not calcium citrate or any of the other acid salts of calcium<sup>1</sup>. Rather, Applicants’ claimed additives comprise a “suspension” of “calcium carbonate powder” in an acidic aqueous solution.

While it is true that, under the appropriate conditions, calcium carbonate *can* react with organic acids, such as citric acid, to form salts, such as calcium citrate, that is not the claimed invention. A review of the present specification makes clear that Applicants are not claiming calcium citrate or any other reaction product of calcium carbonate. Preparative Example 2, for instance, teaches that “[t]he calcium additive had the consistency of a uniform aqueous suspension of fine calcium carbonate powder.” [p. 21]. Further, the application teaches that it is an unexpected result that calcium carbonate powder remain as “relatively stable calcium carbonate suspensions” in acidic solution rather than undergoing reaction with the acid. [pp. 6-7]. Thus, despite the fact that calcium carbonate and acid are present together, the bulk of the calcium carbonate remains unreacted (i.e., it remains in “powder” form). Further, the aqueous suspensions remain acidic over the period in which the additive is made and used, evidencing the fact that acid also remains unreacted.

This is best illustrated by the data presented in Table 1 on page 19 showing that , in the case of fumaric acid, for example, the pH only rises from 5.10 to 5.47 over the entire ten minute mixing period. The visible presence of insoluble calcium carbonate powder after 10 minutes of mixing, coupled with the acidic pH (5.47), demonstrates that, for whatever reason, a

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<sup>1</sup> However, as taught in the application, “the formation of calcium salts in low to moderate amounts is not deleterious to the practice of the invention as long as the pH of the solution remains sufficiently acidic such that the properties of dough will not be adversely affected upon addition of the calcium additive.” [p. 7].

relatively stable suspension of calcium carbonate powder is formed. Were the components to react to form a salt, as suggested by the Examiner, the acid would be consumed resulting in a basic (>7) pH since there is an excess of basic calcium carbonate. Surprisingly, that is not what is observed, nor is it what is claimed.

Respectfully, the Examiner appears to be substituting an alternate view of the chemistry while appearing to ignore the language of the claims. The cited patents do not teach or suggest dough additives comprising suspensions of calcium carbonate powder in an acidic medium.

### **Claim Rejections**

#### **U.S. Patent No. 6,228,161 ("Drummond")**

Claims 1 and 8 are rejected under § 103 as obvious over U.S. Patent No. 6,228,161 ("Drummond"). Specifically, the Examiner states that Drummond "discloses a calcium carbonate stabilized acid slurry, which has a pH of less than 6 containing water, calcium carbonate, and a weak acid." The Examiner correctly observes that Drummond does not disclose the "particular ratio of calcium carbonate to acid" recited in Applicants' claims, but argues that "the reference discloses that enough calcium compound is used to make a pH of less than 7, even though 6 is preferred" and therefore "it would have been obvious to make a product at within the claimed ratio to make a pH of about 6.5."

Applicants respectfully submit that this rejection is improper because Drummond is nonanalogous art and thus cannot be the basis of a § 103 rejection. In order to rely on a reference outside of the field of endeavor to which Applicants' application pertains, the Examiner must rely only on analogous prior art. See M.P.E.P. § 2141.01(a). Notwithstanding, the Examiner states that "In this day of data bases, it is easy to find various compositions in the

data base, that are not analogous, but nothing is seen to keep one using a known composition as a calcium additive since it contains calcium” [Office Action, p. 7]. Applicants respectfully submit that the ease with which a data base may be searched is irrelevant to the obviousness inquiry. Rather, the law is clear that the Examiner can only rely on analogous art as the basis for an obviousness rejection. see In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (holding that “analogous art” is art to which a person of ordinary skill, seeking to solve the problem addressed by the subject application, “would be expected or motivated to look”).

Drummond is directed to paper-making, not foods and baking. A review of the baking art directed to calcium enrichment highlights the fact that the skilled artisan would not look to a product intended “as a filler in neutral or acid paper to improve the optical properties of the paper” (Drummond, col. 1, lines 7-9) and have a reasonable expectation that such a product would be suitable for enriching baked products with calcium. It is well known in the art that calcium additives, including calcium carbonate, can adversely alter the chemistry and organoleptic properties of baked products. For example, U.S. Patent No. 5,945,144, entitled “Calcium fortified pasta and process of making,” teaches:

However, as with most foods, one cannot just modify the level of one ingredient without concomitantly investigating the effect on the organoleptic properties of the pasta. After all, it is axiomatic in the food industry that the mere addition of an ingredient would have no beneficial import unless the aesthetic quality of the food is accepted by the consumer. The objective is therefore to add the calcium to the pasta and, at the same time, maintain or improve the organoleptic properties of the pasta, including color, texture, firmness, taste, stickiness, compressibility, and the like. (emphasis added) [U.S. Patent No. 5,945,144, col 1., lines 55-67].

Similarly, U.S. Patent Pub. 2006/0073237, entitled “Calcium supplementation of foodstuffs,” teaches:

However, calcium supplementation of foodstuffs is not a straightforward matter of adding calcium or a derivative thereof to a foodstuff. For example, calcium hydroxide and calcium carbonate are available for addition to foodstuffs, and are relatively inexpensive. However, both forms of calcium typically interact with a foodstuff, especially an acidic foodstuff. This interaction typically is deleterious to product appearance, flavor, and presentation. (emphasis added) [U.S. Patent Pub. 2006/0073237, ¶ 0008]

U.S. Patent Pub. 2005/0238760, entitled “Food products fortified with calcium and method of preparation,” also highlights the unpredictability of adding calcium carbonate to baked products. This publication teaches that:

One approach is to providing higher levels of calcium fortification is to employ calcium carbonate as the calcium ingredient . . . However, puffed R-T-E cereals are especially difficult to fortify with high levels of calcium incorporated into the cooked cereal dough. For example, when CaCO<sub>2</sub> is used to provide the calcium, the calcium ingredient acts as a leavening agent and can cause over leavening of the puffed pieces even when conventional leavening ingredients are not added. Both product appearance and texture can be adversely affected. Counterintuitively, over leavening can actually result in under expansion. [U.S. Patent Pub. 2005/0238760, ¶¶ 0006-0007].

These contemporaneous disclosures evidence the complexity involved in fortifying foods with calcium, both in terms of the chemistry of the product (e.g., leavening) and the organoleptic properties (e.g., taste and texture). In view of this complexity, the skilled practitioner would not be motivated to look to the paper-making arts and would not have a reasonable expectation that a product intended to improve the optical properties of paper would

be suitable for enriching baked products with calcium for its nutritive value. For this reason, Applicants submit that the rejection is improperly based on hindsight because, without the benefit of the present disclosure, one skilled in the art would clearly not be motivated to look to and modify the nonanalogous paper-making fillers of Drummond for incorporation in baked products.

Nevertheless, in order to advance prosecution in this case, claim 1 has been amended to incorporate the limitation of claim 10 requiring that “the calcium carbonate is provided as a powder having a mean particle diameter from about 0.05  $\mu\text{m}$  to about 30  $\mu\text{m}$ .” The Examiner has not rejection claim 10 over Drummond in either the September 14, 2005 or February 1, 2006 Office Actions. Accordingly, the rejections over Drummond are respectfully overcome.

U.S. Patent No. 5,108,761 (“Andon”)

Claims 1-20 stand rejected under § 103 as obvious over U.S. Patent No. 5,108,761 (“Andon”). The Examiner states that Andon discloses “an acidic beverage containing calcium citrate maleate” and argues that the amounts of the ingredients are within the claimed ranges. Applicants respectfully request reconsideration of this rejection.

First, Andon does not teach or suggest the limitations of Applicants’ claims. As discussed above, the claimed invention is not the reaction product of calcium carbonate and acid, but rather involves water-insoluble calcium carbonate powder in suspension in an acidic medium. In contrast, Andon relates to a specific water-soluble calcium salt, “calcium citrate malate.” The Examiner states that “[n]othing has been shown that the calcium citrate malate of the beverage would not have acted the same in bread, using the ratios of Andon.” Applicants submit that whether “calcium citrate malate” would be suitable as a bread additive is irrelevant,

because that is not what is claimed. Applicants fail to find any teaching or suggestion in Andon of the claimed calcium carbonate suspensions.

Further, Andon not only fails to teach or suggest the limitations of Applicants' claims, but in fact teaches away from the claimed subject matter in several respects. Andon teaches that the calcium citrate malate salt is prepared by mixing calcium carbonate with citric acid and malic acid "until all of the calcium appears to have dissolved." Thus, it is clear that Andon uses conditions under which calcium carbonate completely reacts with citric acid and malic acid to form a new salt, "calcium citrate malate." Thus, not only does Andon not teach or suggest using suspensions of calcium carbonate powder as additives, it clearly teaches away from doing so because it states that "it is necessary to mix until all of the calcium appears to have dissolved." (emphasis added) [col. 4, lines 19-29]. If one followed the instructions of Andon, an acidic suspension of calcium carbonate would not result.

Also, Andon teaches that "calcium citrate malate represents a soluble form of calcium, which is considerably more soluble than calcium citrate, calcium malate, or calcium carbonate." [col 5, lines 18-22]. This is a critical feature of Andon's compositions, as they are intended as beverage additives. In contrast, Applicants' claims are directed to a "suspension" of calcium carbonate "powder." Applicants have found that it is desirable to add calcium carbonate to dough in a particulate form (i.e., "powder") in order to minimize adverse effects on dough chemistry. Andon therefore clearly teaches away from the claimed suspensions and methods for this reason as well.

Further, independent claims 1, 12, 21, and 42 require a specific weight ratio of calcium carbonate to acid, namely, "about 4:1 to about 7:1." Contrary to the Examiner's assertion, Andon does not disclose compositions having a ratio of calcium carbonate to acid

within the claimed ranges. The ratios of calcium carbonate to acid disclosed in Andon are molar ratios rather than weight ratios. When converted to weight ratios, the compositions of Andon have very different amounts of calcium carbonate and acid than those of the present claims. For instance, Example 1 of Andon discloses a composition having 200 g of calcium carbonate, 192 g of citric acid, and 201 g of malic acid. This represents a weight ratio of calcium carbonate to acid of approximately 1:2. Therefore, Andon does not fairly teach or suggest Applicants' claimed weight ratios of calcium carbonate to acid, viz., 4:1 to 7:1. Rather, Andon actually teaches away from the ratios in Applicants' claims. On a molar basis, Andon employs an equivalent or excess amount of acid. [col. 3, lines 58-65]. This would appear to be a critical feature of the compositions because Andon teaches that "it is necessary to mix until all of the calcium appears to have dissolved." (emphasis added) [col. 4, lines 19-29]. That is, the stoichiometry of Andon is such that there is complete reaction between calcium carbonate and the acids. This is the opposite of Applicants' invention which seeks to avoid the consumption of calcium carbonate powder and acid. One could not obtain the claimed suspensions using the methods of Andon and would have no motivation to modify Andon to increase the amount of calcium carbonate, as Andon requires complete reaction of calcium carbonate. Applicants therefore submit that Andon's weight ratios teach away from those recited in Applicants' claims.

For at least the foregoing reasons, Applicants' submit that Andon has no relevance to the patentability of Applicants' claims.

U.S. Patent No. 5,260,082 ("delValle")

Claims 21-47 stand rejected under § 103 as obvious over Andon in view of U.S. Patent No. 5,260,082 ("delValle"). Applicants respectfully request reconsideration of this ground of rejection.



With respect to independent method claim 21, directed to a method of fortifying dough with calcium, the Examiner argues that delValle discloses “that it is known to incorporate a slurry of calcium citrate into baked doughs” and therefore it would have been obvious to incorporate a modification of the Andon and delValle compositions into dough. Further, the Examiner argues that independent method claim 42, directed to a method of fortifying a hamburger bun with calcium, would have been obvious over delValle’s disclosure of bread products.

The combination of Andon and delValle does not render independent method claims 21 and 42 obvious because the references do not, alone or in combination, teach or suggest every element of independent method claims 21 and 42. For example, neither Andon nor delValle disclose dough additives comprising calcium carbonate, as required by the present claims. Therefore, this combination of references is clearly deficient.

As discussed above, Andon relates to a specific water-soluble calcium citrate malate salt as an additive to beverages. Andon does not disclose additive compositions having: (1) “calcium carbonate powder suspended in said aqueous solution of an inorganic or organic acid,” (Andon describes the water-soluble salt “calcium citrate malate”); or (2) that “the weight ratio of calcium carbonate to acid is from about 4:1 to about 7:1,” (Andon’s compositions have a weight ratio of calcium carbonate to acid of approximately 1:2), and, in fact, teaches away from both of these features.

DelValle does not rectify the deficiencies of Andon because, among other reasons, it does not teach an additive comprising calcium carbonate. DelValle discloses the reaction product of a calcium salt, such as calcium carbonate, with citric acid. [col. 2, lines 28-31]. As explained in delValle, the product is prepared by “neutralizing citric acid with a slurry

of calcium carbonate.” [col. 2, lines 41-47]. DelValle, like Andon, relates to the product of reaction of calcium carbonate and acid. This is very different from Applicants’ claimed invention which requires “calcium carbonate powder suspended in said aqueous solution of an inorganic or organic acid,” rather than the reaction product which results under the specific conditions described in delValle.

Also, DelValle does not disclose compositions wherein “the weight ratio of calcium carbonate to acid is from about 4:1 to about 7:1” DelValle provides the ratios of calcium salt to citric acid as molar ratios rather than weight ratios. However, delValle uses ratios of calcium to acid which are very different from the claimed weight ratios. For example, delValle Example 1 discloses the reaction product of calcium hydroxide and citric acid in a molar ratio of 2.29:2. In the case of calcium carbonate, this molar ratio would correspond to a weight ratio of calcium carbonate to acid of about 1:1.83.<sup>2</sup>

The Examiner has provided no motivation to depart from the explicit teachings of Andon and delValle. The Examiner’s assertion that “the weight ratio is seen as being within the skill of the ordinary worker” (Office Action, p. 7) is not sufficient to provide a suggestion to modify the methods of Andon and delValle. As explained in MPEP § 2143.01:

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. (emphasis added)

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<sup>2</sup> Calcium carbonate has a molecular weight of 100.09 g/mol and citric acid has a molecular weight of 210.14 g/mol. Thus 2.29 moles of calcium carbonate weighs 229.2 g and 2 moles of citric acid weight 420.29 g, yielding a weight ratio of 1:1.83.

Rather, the Examiner must show that “the prior art also suggests the desirability of the combination.” MPEP § 2143.01. The Examiner has not provided any motivation for modifying the ratios of calcium carbonate to acid in Andon or delValle. In fact, to do so would go against the explicit teaching of those patents.

Further, the skilled artisan would not have a reasonable expectation that the suggested combination would be successful. Applicants direct the Examiner’s attention to Example 2 of delValle which compares the pH of 1% aqueous slurries of delValle’s spray-dried calcium citrate additive with slurries prepared from commercially available calcium citrate salt. DelValle’s calcium citrate is shown to provide a pH from 3.95 to 7.28 (acidic to neutral), depending on the molar concentration of calcium and citrate, whereas commercially available calcium citrate yielded a pH of 9-11 (basic). The unique properties of delValle’s calcium citrate additives are said to be “attributable to the particle size of the salt crystals, relying almost completely on the shape, number and geometrical arrangement of the calcium citrate crystals as they disperse in the water phase of the new food compositions of the invention.” [col. 4, lines 21-28]. Thus, delValle is limited to a very specific method of preparation and one would not reasonably expect that modification of delValle’s compositions would preserve their ability to provide acidic slurries. As explained in MPEP § 2143.01, “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”

Additionally, the additives of Andon (calcium citrate malate) and delValle (crystalline calcium citrate) are very different compositions. The calcium citrate malate of Andon is a water soluble calcium salt used as an additive for beverages whereas the calcium citrate of delValle is a water insoluble calcium salt for addition to baked goods. One would not

look to this combination because the additives are very different in composition, properties, and intended use.

With respect to independent claim 36, Applicants submit that delValle does not disclose a bread product having elemental calcium from 1.2 % to 2.2 % by weight. Further, there would be no motivation to make a bread product having this calcium content because the additives of delValle are not added for their nutritive value.

In sum, neither Andon nor delValle, alone or in combination, teach or suggest every limitation of the present claims for at least the reason that neither reference discloses an additive comprising calcium carbonate. Thus, the combination of Andon and delValle fails to establish a prima facie case of obviousness. See MPEP 2143.03. (“To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.”).

In light of the amendments and remarks, Applicants respectfully request withdrawal of all rejections.

Applicants do not believe it is necessary at this time to further address the rejections of the dependent claims, as Applicants believe that the arguments and amendments place the independent claims in condition for allowance. Applicants reserve the right to address those rejections in the future, if necessary.

### **CONCLUSION**


Applicants respectfully submit that this application is in condition for allowance. If a telephone conference would facilitate prosecution in any way, the Examiner is invited to contact the undersigned at the number provided.

AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4517-4003. In the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account and Order No. 4517-4003. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

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